

**REMARKS**

Claims 1 - 11 are presently pending, and are rejected. Claim 1 has been amended to clarify the claim language. Support for the amendment may be found throughout the specification, e.g., at paragraphs [0007], and [0011].

The present invention is directed to a method for influencing the behavior in an animal. The method comprises feeding to the animal a diet comprising at least about 0.5% by weight of an omega-3 fatty acid or mixture of omega-3 fatty acids.

**I. 35 USC § 102(b) rejection**

Claims 9 and 10 are rejected under 35 USC § 102(b) as being anticipated by Ishihara et al. (US 6,297,280). The Examiner asserts that Ishihara teaches compositions for suppressing behavior problems in pets, for example, administration of a powder composition comprising 5% DHA to cats exhibiting behavior problems, and administration of compositions comprising 5% DHA to dogs with an average age of 1.7 years with behavior problems associated with heatstroke.

Applicants respectfully traverse the rejection and request it be withdrawn, as Ishihara fails to disclose all the limitations of the claims. An "anticipating" reference must describe all of the elements and limitations of the claim in a single reference, and enable one of skill in the field of the invention to make and use the claimed invention. *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378-79 (Fed. Cir. 2001); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226 (Fed. Cir. 1989). Anticipation is established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention. *RCA Corp. v. Applied Digital Data Sys. Inc.*, 2212 USPQ 385, 388 (Fed. Cir. 1984).

Applicants respectfully submit that Ishihara cannot anticipate the instant invention as the cited reference simply does not teach the claimed method of influencing the behavior in an animal by feeding to the animal a diet comprising at least about 0.5% to about 10% by weight of an omega-3 fatty acid or mixture of omega-3 fatty acids.

A closer reading of Ishihara reveals that the animals were not fed diets comprising 5% DHA. Ishihara fed nine cats commercially available cat foods with *supplements* (col. 7, example 2). Specifically, cats BB, GG and HH were not fed diets comprising 5% DHA; rather, cat foods were *supplemented* with specific amounts of "Sun Coat DY-5," which has a DHA content of 5%. Sun Coat DY-5 may contain a total DHA concentration of 5%, but the cats actually received foods containing less than this amount. Similarly, dogs BBB, GGG, and HHH were fed foods *supplemented* with specific amounts of Sun Coat DY-5 which has a total DHA content of 5%; the dogs were not fed diets comprising 5% DHA. Thus, Applicants respectfully submit that the Examiner's interpretation of Ishihara is in error. Indeed, cats BB, GG, HH, and dogs BBB, GGG, and HHH could not *all* have been fed a diet comprising 5% DHA because the *amounts* of Sun Coat DY-5 supplementing their foods is *different*.

As Ishihara fails to disclose all the limitations of claim 9 and dependent claim 10, Applicants respectfully request that the rejection be withdrawn.

## II. 35 USC § 103(a) rejections

### A. Claim 11 is rejected under 35 USC § 103(a) as being unpatentable over Ishihara et al. (US 6,297,280).

The Examiner asserts that Ishihara teaches compositions for suppressing behavior problems in pets, for example, by administration of a powder composition comprising 5% DHA to cats exhibiting behavior problems, and by administration of compositions comprising 5% DHA to dogs with an average age of 1.7 years with behavior problems associated with heatstroke. Furthermore, the Examiner alleges that Ishihara further teaches that highly unsaturated fatty acids includes EPA and DHA, and that DHA compositions may be formulated with EPA; however Ishihara does not illustrate administration of compositions with EPA. The Examiner believes that it would be obvious to one of skill in the art to modify the teachings of Ishihara to administer a DHA composition with EPA to influence the behavior of pets, and thus teach the present invention.

The Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness, and respectfully request that the rejection be withdrawn. According to the Federal Circuit, in order to establish a case of obviousness, three basic criteria must be met.

There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. There also must be a reasonable expectation of success, and, finally, the prior art reference must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art and not in the Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP 2143. The Supreme Court recently recognized that a showing of "teaching, suggestion, or motivation" to combine prior art could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 USC 103(a). *KSR Int'l. Co., v. Teleflex, Inc.*, No. 04-1350 (U.S. Apr 30, 2007). The Supreme Court specifically stated that "it will be necessary . . . to determine whether there was an apparent reason to combine [or modify] the known elements [in the prior art] in the fashion claimed by the patent at issue. To facilitate review, this analysis *should be made explicit*." *Id.* at slip opinion 14 (emphasis added).

Applicants have previously discussed the disclosure of Ishihara, and how it fails to disclose every limitation of the claims, e.g., Ishihara fails to disclose compositions having from about 0.5% to about 10% by weight of an omega-3 fatty acid or mixture of omega-3 fatty acids. As Ishihara fails to disclose or suggest diets comprising from about 0.5% to about 10% by weight of an omega-3 fatty acid or mixture of omega-3 fatty acids, it cannot disclose or suggest the narrower limitation in claim 11 of from about 1% to about 5% by weight of a mixture of EPA and DHA. Thus, Applicants respectfully request that the rejection be withdrawn.

Additionally, a person having ordinary skill in the art would not have been motivated to modify the DHA compositions of Ishihara with a mixture of DHA and EPA, as Ishihara fails to teach or suggest that DHA alone is effective in influencing the behavior of the animals. Rather, DHA is used by Ishihara to supplement theanine to suppress the behavior problems of pets. This is made clear in the specification which states: "the present inventors have found that a composition comprising a theanine, and *optionally further comprising* one or more compounds selected from the group consisting of highly saturated fatty acids... can suppress the behavior of pets...." Col. 2, lines 3 - 7 (emphasis added). Ishihara also indicates:

[I]t is preferable that the composition of the present invention further comprises one or more compounds selected from highly unsaturated fatty acids and cholines. Although the function

mechanism is not clarified, the compounds [highly unsaturated fatty acids and cholines] can act to *enhance* the action of the suppressing behavior problems owed by theanine. Therefore, the same level of effects as that exhibited with theanine alone can be obtained, with a smaller dosage of theanine required as compared to the case where theanine is used alone by the *copresence* of the compounds.

Col 2, lines 63 - 67 (emphasis added). Furthermore, Ishihara makes it clear that, "[t]he process for preparing the composition of the present invention is not particularly limited, *as long as the composition can comprise theanine....*" Col 4, lines 14 - 16 (emphasis added).

In addition, a review of Ishihara's data gives no indication that an omega-3 fatty acid or mixture of omega-3 fatty acids is effective in influencing the behavior of pets in the absence of theanine. As presented in "Test Example 2" and accompanying Table 4 (cols. 7 - 8), various supplements were added to the commercially available pet foods. Cats BB, CC and DD all received 1.7 mg/day of theanine (prepared in Example 1), however, cat BB also received 83 mg/day of Sun Coat DY-5, and cats CC and DD also received arachidonic acid and phosphatidylcholine, respectively. The data shown in Table 4 indicates that level of suppression of the behavior problems in cats BB, CC and DD were identical. One of skill in the art would not interpret this to mean that DHA has an effect on influencing behavior, rather, one can only say that theanine administered with Sun Coat DY-5 has the same effect as theanine administered with arachidonic acid or phosphatidylcholine. The fact that theanine administered with Sun Coat DY-5 has the same effect as theanine administered with arachidonic acid and phosphatidylcholine is further supported by the results of dogs B, C and D of Test Example 1 (cols 6 - 7), dogs BBB, CCC and DDD of Test Example 3 (cols 8 - 9), dogs K, L and M of Test Example 4 (cols 9 - 10), and dogs KK, LL and MM of test example 5 (cols 10 - 11). Referring to Test Example 5's Table 7 at column 11, one of skill in the art may even infer that theanine with phosphatidylcholine (dog MM) has a greater impact on dogs suffering from dementia than theanine and DHA (dog KK) or theanine and arachidonic acid (dog LL). Based on these results, one of skill in the art would not recognize that DHA alone influences the *behavior* of animals.

There is no reasonable expectation of success in practicing the claimed invention based on the disclosure of Ishihara. There is no data in Ishihara to suggest that DHA alone is effective in influencing behavior in an animal, thus there would also be no reason to expect that a mixture

of DHA and EPA would be effective in influencing the behavior of animals at the levels disclosed by Ishihara.

All together, a person of skill in the art would not be motivated to influence the behavior of animals by administering a diet having a mixture of DHA and EPA because Ishihara fails to even disclose that DHA alone is effective in influencing a pet's behavior, and thus there is no reasonable expectation of success in influencing the behavior of animals by feeding them a diet comprised of a mixture of DHA and EPA. There is no reason why a person of ordinary skill in the art would have modified Ishihara to produce the claimed invention. Finally, Ishihara fails to disclose or suggest all the limitations of the claim. Thus, the Examiner has not demonstrated that claim 11 is obvious in view of the disclosure of Ishihara, and Applicants respectfully request that the rejection be withdrawn.

**B. Claims 1 - 7 and 9 - 10 are rejected under 35 USC § 103(a) as being unpatentable over Davenport et al (A) (WO 2004/006688A1) in view of Davenport et al (B) (US 2003/0194478A1).**

Davenport (A) teaches a method for moderating the behavior of a healthy dog living in an animal shelter by feeding the healthy dog a high quality diet containing a high amount of DHA and EPA. Such compositions comprise from about 0.15% to about 0.25% DHA, and another composition may contain from about 0.15% to about 0.25% EPA; however, Davenport (A) does not teach administration of a formulation comprising at least about 0.5% DHA and EPA for influencing the behavior in an animal.

Davenport (B) teaches a method for increasing the hunting performance of an animal, which includes administering a diet comprising unsaturated fatty acids in an amount greater than about 0.20% weight. Davenport (B) further teaches that the composition may have total amount of unsaturated fatty acids EPA, DPA, and DHA in about 0.50% to about 0.55% weight.

The Examiner asserts that it would have been obvious to combine the teachings of Davenport (A) with Davenport (B), as Davenport (B) teaches that a composition comprising 0.5 to 0.55% unsaturated fatty acids is safe and effective, and Davenport (A) teaches two different compositions having EPA up to 0.25%, and DHA up to 0.25% are useful for influencing behavior. According to the Examiner, "[o]ne would have been motivated to employ the maximum amount of each of DHA and EPA as taught by Davenport (A) in a single composition

with a reasonable expectation of success in influencing the behavior of an animal in order to achieve a highly unsaturated fatty acids that is safe and effective for the animals as taught by Davenport (A) and (B). January 3, 2007 Office Action, page 6. Applicants respectfully traverse the rejection and request reconsideration, as the Examiner has not established a *prima facie* case of obviousness.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. There also must be a reasonable expectation of success, and the prior art reference (or combined prior art references as the case may be) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art and not in the Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP 2143. The Supreme Court recently recognized that a showing of "teaching, suggestion, or motivation" to combine prior art could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 USC 103(a). *KSR Int'l. Co., v. Teleflex, Inc.*, No. 04-1350 (U.S. Apr 30, 2007). The Supreme Court specifically stated that "it will be necessary . . . to determine whether there was an apparent reason to combine the known elements [in the prior art] in the fashion claimed by the patent at issue. To facilitate review, this analysis *should be made explicit*." *Id.* at slip opinion 14 (emphasis added).

In this case, there is no motivation to combine the teachings of Davenport (A) and Davenport (B). Davenport (A) teaches in one embodiment the high quality diet may contain DHA levels of from about 0.05% to about 0.25% in the diet, and teaches in another embodiment that a diet may contain EPA levels from about 0.05% to about 0.25% of the diet. A person having ordinary skill in the art would read and understand that Davenport (A) has already taught moderating the behavior of healthy dogs living in animal shelters by administering a diet containing 0.25% DHA, or a diet containing 0.25% EPA; thus, there is no need to provide both. Accordingly, there is no motivation to refer to the teachings of Davenport (B) to produce a single composition comprising at least about 0.5% of an omega-3 fatty acid or mixture of omega-3 fatty acids.

The Examiner asserts that one of skill in the art would be motivated to use Davenport (B) for the proposition that administration of 0.5% to about 0.55% DHA and EPA is safe and effective for hunting dogs, and thus would be expected to be safe and effective for the dogs in Davenport (A) experiencing behavior problems. According to the Examiner, Davenport (B) teaches a method for increasing the hunt performance of a dog, including perception, responsiveness, alertness, and target detection of a hunting animal. Applicants respectfully submit, however, that the focus of Davenport (B) is physiological, rather than behavioral. Davenport (B) teaches a diet having a total amount of unsaturated fatty acids EPA, DPA and DHA of about 0.5 to about 0.55 weight percent (page 9, claim 47). However, claim 47 depends from claim 8 (page 8), which is directed to a method for increasing the heat endurance of a hunting mammal. "Heat endurance" is not specifically defined by Davenport (B); however, one may understand what is intended by referring to the specification. "The lower or cooler post-hunt body temperature suggests the dogs expend less energy on waste heat and consequently have greater endurance and greater energy available for hunt related tasks...." Page 7, paragraph 66. "The present invention [of Davenport (B)] provides a dietary composition administered to avoid or prevent heat exhaustion, such as overheating or heat stroke...." Page 3, paragraph 39. Thus, one of skill in the art would understand that increasing the heat endurance of an animal involves preventing overheating or heat stroke so that an animal may continue with a hunt.

In contrast, the present application seeks to *influence behavior*, and is not directed to an animal's thermoregulation. Given Davenport (B), one of skill in the art would simply not be motivated to administer a composition comprising at least about 0.5% by weight of an omega-3 fatty acid or mixture thereof to an animal to influence behavior. The composition disclosed in Davenport (B) is described for use to treat heat stroke; there is nothing in the reference which teaches or suggests that a composition having 0.5% by weight of omega-3 fatty acids is *effective* to influence behavior as claimed in the instant invention, or even as described in Davenport (A). Applicants respectfully submit that as Davenport (B) fails to teach or suggest use of omega-3 fatty acids to influence *behavior*, there clearly is no reasonable expectation of success that a combination of omega-3 fatty acids may be used according to the methods of the present invention.

As there is no motivation to combine the teachings of Davenport (A) and Davenport (B) to practice the claims of the instant invention, and there is no reason why a person of ordinary

skill in the art would have combined the prior art elements, Applicants respectfully request that the rejection be withdrawn.

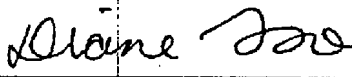
Applicants respectfully submit that the application is now in condition for allowance, and therefore respectfully request that the outstanding rejections be withdrawn and that a Notice of Allowance be issued.

It is believed no fee, other than a one-month extension of time, is required. If additional fees are required, please charge the same to Deposit Account 50-2957.

Respectfully submitted,

Date: May 3, 2007

By



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